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EXAMINER	
KIM, TAEYOON	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/24/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/700,355	STREETER, JACKSON	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13 and 16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11-13 and 16-19 are pending.

Response to Amendment

Applicant's amendment and response filed on Jan. 29, 2007 has been received and entered into the case.

Claims 1-10, 14 and 15 have been canceled, claims 11-13 and 16-19 are pending and have been considered on the merits. All arguments have been fully considered.

The rejections under 35 U.S.C.§112, 2nd paragraph and 35 U.S.C.§102(b) have been withdrawn due to the amendment.

The declaration under 37 CFR 1.132 filed Jan. 29, 2007 is insufficient to overcome the rejections based upon a statutory bar under 35 U.S.C.§102(b) as set forth in the last Office action because: M.P.E.P. §2136.05 states "[a] prior art reference that is **not a statutory bar** may be overcome by two generally recognized methods": an affidavit under 37 C.F.R. 1.131, or an affidavit under 37 CFR 1.132 "showing that the relevant disclosure is a description of the applicant's own work"); In re Facius, 408 F.2d 1396, 1407, 161 USPQ 294, 302 (CCPA 1969)"

Response to Arguments

Applicant's arguments filed on Jan. 29, 2007 have been fully considered but they are moot upon the amendment. However, the examiner would like to point out that even though the teaching of Salansky et al. of activating production of immunoglobulins in the immune system is purely in vivo effect as applicant argued in the response, the

limitation is drawn to an intended use of vaccine production and nothing to do with the claimed invention of method. Therefore, this argument alone, regardless the declaration under 37 C.F.R. 1.132, would not be sufficient to overcome 102(b) rejection.

Applicant argues that the reference of van Breugel teaching in vitro human fibroblast cells which produce collagen would not be useful in the production of a vaccine and person of ordinary skill in the art would know that such cells are not useful in the production of a vaccine. This argument contradicts what the applicant discloses in the specification as well as a statement in the declaration under 37CFR 1.132. Applicant stated that "providing an in vitro cell culture comprising cells useful in production of a vaccine" includes providing an in vitro cell culture which comprises: (i) cells or cell fragments which can be introduced into a host body to trigger production of antibodies by the host body, and/or (ii) cells which produce compounds which can be introduced into a host body to trigger production of antibodies by the host body. Since any cell can be introduced into a host body to trigger production of antibodies, unless it is autologous to the host, cells useful in the production of a vaccine encompass any type of cells including human fibroblast cells. Thus, this argument cannot overcome a statutory bar under 35 U.S.C. §102(b). However, this argument is moot because of the current amendment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-13 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salansky et al. (US 6,063,108).

Claims 11-13 and 17-19 are drawn to a method for accelerating the production of vaccine by an in vitro cell culture comprising 1) providing an in vitro cell culture comprising cells, and 2) delivering an effective amount of electromagnetic energy to the cell culture comprising a power density of at least about 0.01 mW/cm^2 and a wavelength of about 780 nm to about 840 nm (claim 11); a limitation to the power density being about 0.01 to about 100 mW/cm^2 (claim 12); a limitation to the power density being about 0.01 to about 15 mW/cm^2 (claim 13); a limitation to the delivering step comprising delivering a series of pulses of light (claim 17); a limitation to the delivering step comprising at least two treatment periods (claim 18); a limitation to the delivering step proceeding for a period of about 30 seconds to about 2 hours (claim 19).

It is noted that the limitation of "cells useful in production of a vaccine" has been interpreted as any cell. This is because any cell or cell fragment can be used for vaccine production by introducing into a host.

Salansky et al. teach a method delivering an effective amount of electromagnetic energy with a wavelength of 800 nm (column 3, line 48) to cell culture (see column 8, lines 22-25), wherein light energy having a power density at the range of 0.2-10 mW/cm^2 (see table 2). Salansky et al. also teach the delivery electromagnetic energy with a light energy can be multiple treatment periods (see Table 9) and the duration of pulse (exposure time) is disclosed as 300-400 seconds (see Table 8).

The limitations of "useful in production of a vaccine", "accelerating the production of a vaccine" and "wherein the delivering the electromagnetic energy results in the enhancement or improvement of..." in the claims are not considered as limiting subject matters because these are not considered as active steps to be performed in the method or limiting a claim to a particular structure. M.P.E.P. §2106 states "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

(A) statements of intended use or field of use,

(B) "adapted to" or "adapted for" clauses,

(C) "wherein" clauses, or

(D) "whereby" clauses.

This list of examples is not intended to be exhaustive. See also MPEP § 2111.04.

Nevertheless, as Salansky et al. disclose that electromagnetic energy irradiation results in activation of cell metabolism, respiration and secretory activity and also protein synthesis (column 26, line 61 through column 27, line 40), which would be useful in production of a vaccine as disclosed in the specification of the current application (paragraphs [0003] and [0004]).

The method of Salansky et al. is drawn to both *in vivo* therapy as well as *in vitro* cell culture experiments. Although Salansky et al. disclose the limitations to power density or a wavelength of electromagnetic energy for *in vivo* therapy, but not

particularly for cells in culture, it would have been obvious for a person of ordinary skill in the art at the time of invention made to recognize that the limitations used for *in vivo* therapy were derived from *in vitro* cell culture experiments as Salansky et al. disclose that data from cell culture and animal studies is used for the calculation of required optical parameters for human therapy (see Fig. 1). Thus, it would have been obvious for a person of ordinary skill in the art to recognize that the limitations to the treatment for *in vivo* therapy disclosed in Salansky et al. would have been used for *in vitro* cell culture, and therefore use the parameter in the method of Salansky et al. for *in vitro* cell culture with a reasonable expectation of success.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 11, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Breugel et al. (Lasers in Surgery and Medicine, 1992, 12:528-537).

Claims 11, 12 and 16 are drawn to a method for accelerating the production of vaccine by an in vitro cell culture comprising 1) providing an in vitro cell culture comprising cells, and 2) delivering an effective amount of electromagnetic energy to the cell culture comprising a power density of at least about 0.01 mW/cm^2 and a wavelength of about 780 nm to about 840 nm (claim 11); a limitation to the power density being about 0.01 to about 100 mW/cm^2 (claim 12); a limitation to the delivering step comprising placing a light source above a top surface of a container holding a cell culture (claim 16).

Van Breugel et al. teach a method of laser irradiation to human fibroblasts in culture at a power density in a range of 0.55 to 5.98 mW and the light source was at the top surface of a cell culture incubator (see Abstract and Fig. 1).

Although van Breugel et al. do not teach a method to accelerate production of a vaccine, it is noted that the claims do not require production of a vaccine, but merely state that the cells treated by the method are useful as such. Furthermore, while van Breugel et al. do not particularly teach the method wherein the cells are used for a vaccine, this limitation has been interpreted as an intended use. Similar to the interpretation discussed above, the limitations of "useful in production of a vaccine", "accelerating the production of a vaccine" and "wherein the delivering the electromagnetic energy results in the enhancement or improvement of..." in the claims are not considered as limiting subject matters because these are not considered as active steps to be performed in the method or limiting a claim to a particular structure (see M.P.E.P. §2111.04).

Van Breugel et al. do not teach that the wavelength of electromagnetic energy being about 780 nm to about 840 nm.

The selection of a wavelength at about 780 nm to about 840 nm would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the modification of wavelength in various ranges would be desired to obtain an optimal range of wavelength for the method. A holding of obviousness over the cited claims is therefore clearly required. The normal desire of scientists or artisans to improve upon what is already generally known provides the

motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382.; See also M.P.E.P. § 2144.05

Furthermore it is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re* Aller, Lacey, and Haft, 105 USPQ 233 (CCPA 1955): Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re* Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931,24 USPQ 52; *In re* Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re* Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re* Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re* Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re* Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re* Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11,57 USPQ 136. (Emphasis added). With regards to determining experimental parameters, such as time in culture, the court has held that "[d]iscovery of optimum value of result effective variable in known process is ordinarily within skill of art (In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980)).

The adjustment of particular conventional working conditions (e.g., wavelength) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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